

### **REMARKS**

This amendment is in response to the Official Action dated August 4, 2009. No claims have been amended, no claims have been canceled, and no claims have been added; as such, claims 1-8 are now pending in this application. Claims 1, 4 and 7-12 are independent claims. Reconsideration and allowance is requested in view of the following remarks.

#### **Double Patenting Rejection**

Claims 1-8 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending Application No. 10/569,463.

Applicant does not concede the propriety of these grounds of rejection, and asks that the requirement for a terminal disclaimer be held in abeyance pending the indication of allowable subject matter, so that Applicant can give an assessment at that time of the differences between what is claimed and allowed herein vis-à-vis the '463 application.

#### **35 USC § 102/103 Rejections : Claims 1 and 5**

Claims 1 and 5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gropper et al (US 5,540,220, hereinafter referred to as "Gropper '220") or in the alternative under 35 U.S.C. § 103 (a). Applicant respectfully traverses this rejection.

Claim 1 recites:

*An oxygen supplying apparatus comprising*

*an oxygen generating means,*

*an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and*

*a single automatic closing valve placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising:*

*a respiration sensor which detects the respiration of the user and provides a respiration signal;*

*a supply method setting means which selects the supply in a continuous flow or the supply in synchronism with the respiration of the user;*

*a flow rate setting means for a supply flow rate set value; and,*

*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means.*

Gropper '220 discloses a ventilator that has a pressurized oxygen inlet 12 (col. 5, l. 66) thus **fails** to disclose an oxygen supplying apparatus that has **an oxygen generating means**.

Gropper '220 **fails** to disclose, teach or suggest "**a single automatic closing valve placed on an oxygen-supplying passage which "is controlled by the controlling means"**" based on the selection by "**the supply method setting means**" as to whether the selection is "**the supply in a continuous flow or the supply in synchronism with the respiration of the user.**" Gropper '220 discloses **three valves**, namely, a flow rate selection valve 68, a clinician-adjustable inspiratory flow valve 72 and a clinician-adjustable base flow valve 76, placed on an oxygen-supplying passage.

The flow rate selection valve 68 operates to which select which of the two inlets 70 and 74, the flow rate is adjusted by the valves 72, 76 respectively (col. 8, ll. 38-56). The flow rate selection valve 68 does not select the modes of “*the supply in a continuous flow or the supply in synchronism with the respiration of the user.*”

Gropper ‘220 fails to disclose, teach or suggest “*a respiration sensor which detects the respiration of the user and provides a respiration signal.*” Gropper ‘220 discloses flow sensor 40 and flow sensor circuit 42. The flow sensor 40 generates an analog output signal indicative of instantaneous flow rate of gas inhaled and exhaled by the patient being processed and conditioned by a flow sensor circuit 42 (col. 7, ll. 40-45). Thus, the flow sensor 40 does **NOT** detect respiration of the user. Rather the flow sensor 40 detects flow rate of gas through the patient connector 24. Further, the flow sensor circuit 42 **ONLY** produces a digitized **inhalation flow rate** signal and outputs to a CPU (col. 7, ll. 54-57, col. 16, ll 13-14, col. 16, ll. 62-64). Thus Gropper ‘220 fails to disclose, teach or suggest “*a respiration sensor which detects the respiration of the user” AND “a respiration sensor which provides a respiration signal,” the signal of which includes a signal for both **inhalation and exhalation**.*

Gropper ‘220 fails to disclose, teach or suggest “*a supply method setting means which selects the supply in a continuous flow or the supply in synchronism with the respiration of the user.*” In particular, since, as stated above, Gropper ‘220 fails to disclose, teach or suggest “the supply in a continuous flow.” Rather, Gropper ‘220 discloses limited supply of gas flow **without continuous flow**. Further, since Gropper ‘220 fails to disclose, teach or suggest *a respiration sensor which provides a respiration signal*, Gropper ‘220 fails to disclose, teach or suggest *the supply in synchronism with the respiration of the user.* To the contrary, the “**exhalation**” of the user is “**impeded**” (see col. 15, l. 9) by the Gropper ‘220 device. Thus, Gropper ‘220 teaches away “*a supply method setting means which selects the supply in a continuous flow or the supply in synchronism with the respiration of the user.*”

Gropper ‘220 fails to disclose, teach or suggest “*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or*

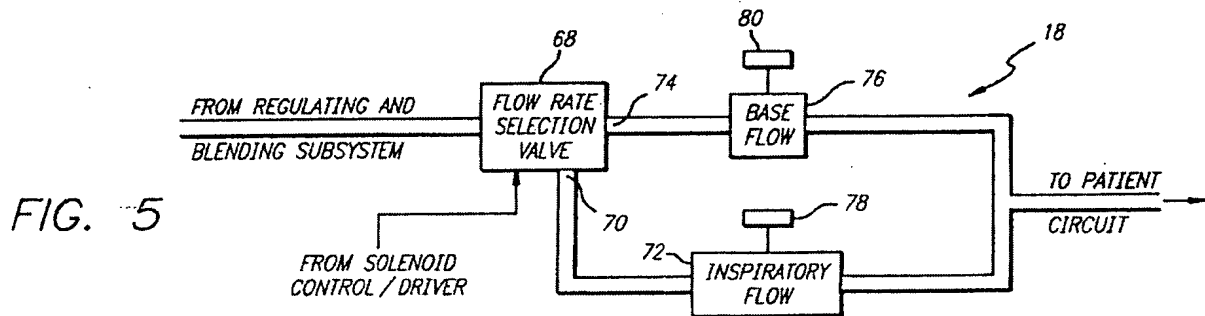
*opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means."*

The Office Action, however, alleges these feature can be found in col. 17, lines 33-36 of Gropper '220. This is wholly inaccurate.

Gropper '220 relates to a method and apparatus for pulmonary ventilation support which represents an improvement in the mode of mechanical ventilation known as "pressure-limited, time-cycled" ventilation (col. 1, ll. 8-13). The pressure-limited, time-cycled pulmonary ventilator of Gropper '220 includes a pressurized gas system that supplies respiratory gas to a patient at a selected inspiratory flow rate; an exhalation valve that (a) opens an expiratory flow path in response to the elapsing of a selected inspiratory time period, and (b) maintains a selected proximal pressure limit during the inspiratory time period; and a volume-cycle override system that actuates the exhalation valve so as to open the expiratory flow path if the patient's tidal volume reaches or exceeds a selected volume limit during the inspiratory time period.

Column 8, lines 37 – 55, of Gropper '220 illustrates the components and function of the flow control subsystem 18 (see FIG. 5 reproduced below). Gas from the regulating and blending subsystem 16 is received in the inlet of a solenoid-actuated flow rate selection valve 68. The flow rate selection valve 68 has two outlets: a first outlet 70 communicates with the inlet of a clinician-adjustable inspiratory flow valve 72, and a second outlet 74 communicates with the inlet of a clinician-adjustable base flow valve 76. Either the first or second outlet of the flow rate selection valve 68 is opened in response to a first solenoid actuation signal generated by the solenoid control/driver circuit 66. The first solenoid actuation signal actuates the flow rate selection valve 68 so as to open its first outlet during inspiratory phase and its second outlet during expiratory phase. In other words, Gropper '220 discloses three valves, namely, a **clinician-adjusted inspiratory**

**flow valve 72 and a clinician-adjusted base flow valve 76 in addition to flow rate selection valve 68.**



Column 17, lines 5 – 31, of Gropper ‘220 discloses the controlling valves dependent on “assist disabled” period. It is stated that if the ventilator is not in the assist disabled period, an algorithm determines if the assist trigger “window” is open; that is, if the ventilator’s operational mode would permit the ventilator to provide machine-assisted breath, that, if the window is open, the assist trigger module 98 of Fig. 4 generates an assist trigger output signal that is inputted to the breath control module 56, that the breath control module 56, in turn, responds by sending a control signal having the first (inspiration initiation) value to the solenoid control driver circuit 66, which, in turn, responds by generating first and second solenoid actuation signals, and that, as a result, the first and second solenoid actuation signals actuate the flow rate selection valve [68] to select the inspiratory flow rate, and the reference pressure selection valve 94 [of pressure reference subsystem 36 (see Fig. 6)] to select the PIP reference pressure.

Col. 17, lines 33-36 of Gropper ‘220 state:

If the ventilator is not in the assist disabled period, the algorithm next determines if the assist trigger “window” is open; that is, if the ventilator’s operational mode would, at that point in the breath cycle, permit the ventilator to provide a machine-assisted breath. If the “window” is open, the assist trigger module 98 generates an assist trigger output signal that is inputted to the breath control module 56. The breath control module 56, in turn, responds by sending a control signal having the first (inspiration initiation) value to the solenoid control driver circuit 66, which, in turn,

responds by generating the first and second solenoid actuation signals having their respective first values, as described above. As a result, as also described above, the first and second solenoid actuation signals actuate the flow rate selection valve 74 to select the inspiratory flow rate, and the reference pressure selection valve 94 to select the PIP reference pressure. The result of these actuations is to cause the ventilator to deliver a machine-assisted breath to the patient.

Clearly, Gropper '220 does NOT teach a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow. In contrast, Gropper '220 discloses three valves, namely, a flow rate selection valve 68, a clinician-adjustable inspiratory flow valve 72 and a clinician adjusted base flow valve 76.

Moreover, the control means of claim 1 controls the aperture of a single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow and opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow.

- **Therefore Gropper '220 fails to disclose, teach or suggest a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means.**

As such, Gropper '220 fails to teach or suggest various features of independent claim 1. For reasons similar to those regarding claim 1, independent claim 5 is similarly neither disclosed nor suggested by Gropper '220.

Accordingly, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 102(b) as being anticipated by Gropper '220 be withdrawn and under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 be withdrawn.

**35 USC § 103 Rejections : Claims 2, 3, 6 and 7**

Claims 2, 3, 6 and 7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gropper '220 in view of the admitted prior art. Applicant respectfully traverses this rejection.

Claims 2, 3, 6 and 7 depend from and thus incorporate the features of claims 1 and 5, which are neither disclosed nor suggested by Gropper '220, for the reasons stated above.

The admitted prior art does not remedy the deficiencies of Gropper '220, as the various features recited above are also absent from the admitted prior art. For example, Applicant's claimed features of "*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means,*" are neither disclosed nor suggested by the admitted prior art.

Accordingly, Applicant respectfully requests that the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 in view of the admitted prior art be withdrawn.

### **35 USC § 103 Rejection : Claims 4 and 8**

Claims 4 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220.

Claims 4 and 8 depend from and thus incorporate the features of claims 1 and 5, which are neither disclosed nor suggested by Gropper '220, for the reasons stated above.

Accordingly, Applicant respectfully requests that the rejection of claims 4 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 in view of the admitted prior art be withdrawn.

### **Conclusion**

In view of the above amendment and remarks, applicant believes the pending application is in condition for allowance.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

### **Extensions of time**

Please treat any concurrent or future reply, requiring a petition for an extension of time under 37 C.F.R. § 1.136, as incorporating a petition for extension of time for the appropriate length of time.



Application No. 10/524,632  
Amendment dated November 3, 2009  
Reply to Office Action of August 4, 2009

Docket No.: TEI-0131

The Commissioner is hereby authorized to charge all required fees, fees under 37 C.F.R. §1.17, or all required extension of time fees.

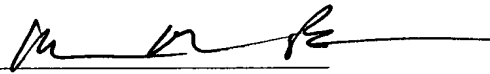
**Fees-general authorization**

The Commissioner is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm).

If any fee is required or any overpayment made, the Commissioner is hereby authorized to charge the fee or credit the overpayment to Deposit Account # 18-0013.

Dated: November 3, 2009

Respectfully submitted,

By 

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